



Putting
the Pieces
Together

The Protection of Human
Subjects in Research
Piece

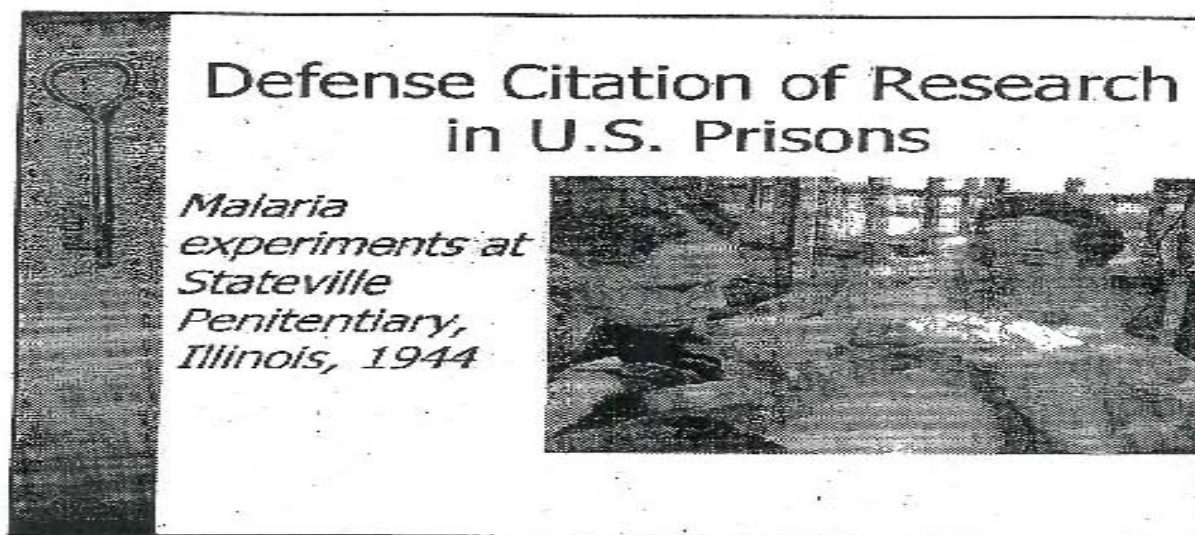
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oshpd



Purpose of the Committee for the Protection of Human Subjects (CPHS)

- To protect the rights of human subjects involved in research projects
- History of human subject abuses
 - Nazi experiments
 - Tuskegee experiment
 - Prisoner research





CPHS Membership

- **Volunteers**
- Up to 13 members
- **Researchers**
- **Community members**
- Representatives of **vulnerable populations**
 - **Prisoners**
 - **Children**
 - **Pregnant women and fetuses**



CPHS Legal Authority and Scope

- CPHS is an **institutional review board**
- Mandated by **federal** and **State** statutes and regulations
- Committee of the CA Health and Human Services **Agency**
- Organizationally located in **OSHDP**



CPHS Review Mandated by Federal Regulations

- In 1970s **Common Rule** (45 CFR 46)
- **Most federal agencies** comply with **Common Rule**



CPHS Reviews Projects

- Involving **human subjects**
- **Funded** by Health and Human Services Agency departments, including OSHPD
- **Directed by or with the assistance of employees** who work for these departments



CPHS Reviews Projects

- Using personally identifiable **data or specimens** held by CHHSA departments
 - **OSHPD has decided that all research requests for non-public data must be reviewed by CPHS**
- Using **subjects** for which CHHSA has custodial responsibility (DMH State mental hospital patients)



Common Rule Review Research/Exemptions

- Researchers may submit to CPHS to determine
 - If project is **research vs. public health practice or program evaluation**
 - If project is research, but **exempt** from CPHS **review**
 - **De-identified data**
- Form is on **website**
(www.oshpd.ca.gov/boards/cphs)



Common Rule Review

- Research design (ethical)
- Risks minimized
- Benefits
- Consent process (voluntary and non-coercive) and waiver of consent)



Common Rule Review

- HIPAA waivers
- Surveys
- Recruitment materials
- Instructions and forms on website
(www.oshpd.ca.gov/boards/cphs)



Common Rule Review

- **Full Committee review**
 - Primary Reviewer assigned
 - Human subject contact -first submission
 - Moderate risk (few projects)
 - Meetings every two months – researchers must attend
 - In person
 - By phone



Common Rule Review

■ Expedited review

- Two reviewers
 - Primary Reviewer
 - Chair or Vice Chair
- Data-Only projects
- Human subject contact projects after first review if minimal risk
- **Turnaround time four weeks**



Common Rule Review

- **Yearly review**, if on-going project
 - **No** ability to provide **extensions to CPHS approval**
 - **No approval, no work on project**
 - **Turnaround is four weeks**

- **Completed and Withdrawn** projects also submitted



Common Rule Review

Data-Only Change?

- **May be changes** to CPHS review of **data-only projects** due to federal guidance changes in definition of engagement in research by department releasing data
 - **Add** requirements for **data security**
 - **Limit reviews** to new, revisions, completed and withdrawn projects – not yearly



CPHS Review Process for OSHPD Data

- CPHS and OSHPD have agreed to require researchers requesting **OSHPD data to:**
 - Submit a **draft protocol to OSHPD** prior to CPHS submission
 - **Initial protocol**
 - **Any revisions**
 - Provides a more streamlined process
 - Prevents delays in approvals



CPHS Review Process for OSHPD Data

- OSHPD data is second most utilized State database utilized for research reviewed by CPHS
- OSHPD data **linked to other databases**, birth and death records
- Data linkages also **reviewed by CPHS**
- If using linked database, include **project approval letter**
- Again, **changes** in CPHS requirements for review of data-only project



CPHS Review Mandated by State Law

- 2005 **Senate Bill 13** amended Information Practices Act (CC 1798.24)
 - Due to a **breach in data security** at UCB
 - Expanded CPHS role to review **all State releases of personal information** to educational institutions for research



SB 13 review

- **Data security**
- Plan to return or **destroy data**
- **Minimum necessary**
- **Unique subject codes** instead of using SS# whenever possible
- **Agency conduct data processing if possible**



SB 13 review

- **Letter of support from department releasing data**
- **Submit to CPHS**
 - **Initial protocol**
 - **More concise than Common Rule**
 - **Revisions**
 - **Complete or withdrawn**
- **Instructions and forms on website (www.oshpd.ca.gov/boards/cphs)**



CPHS Website

- **Provides**
 - **All necessary instructions and forms** for submitting protocols to CPHS
 - **Deadlines and meeting dates**
 - **Links to other sites**
 - **HIPAA**
 - **Office of Human Research Protections**
 - **Common Rule**
 - **SB 13**

www.oshpd.ca.gov/boards/cphs



CPHS Contact Information

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